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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2010-0047]

Monsanto Company and KWS SAAT AG; Determination of Nonregulated Status of Sugar Beet Genetically Engineered for Tolerance to the Herbicide Glyphosate

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that sugar beet genetically engineered for tolerance to the herbicide glyphosate, designated as H7-1, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by the Monsanto Company and KWS SAAT AG in its petition for a determination of nonregulated status, our analysis of publically available scientific data, and comments received from the public on the petition for nonregulated status and its associated environmental impact statement and plant pest risk assessment. This notice also announces the availability of our written determination and record of decision.

EFFECTIVE DATE: [Insert date of publication in the Federal Register].

ADDRESSES: You may read the documents referenced in this notice and any comments we received in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is

there to help you, please call (202) 799–7039 before coming. Those documents are also available on the Internet at http://www.aphis.usda.gov/biotechnology/not_reg.html and are posted with the comments we received on the Regulations.gov Web site at <http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0047>.

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca L. Stankiewicz Gabel, Senior Environmental Protection Specialist, Environmental Risk Analysis Programs, BRS, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1238; (301) 851-3927. To obtain copies of the documents referenced in this notice, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

The regulations in 7 CFR part 340, “Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,” regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered “regulated articles.”

The regulations in § 340.6(a) provide that any person may submit a petition to APHIS seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

On October 19, 2004, APHIS published a notice in the Federal Register (69 FR 61466-61467, Docket No. 04-075-1) announcing receipt of a petition from the Monsanto Company (Monsanto) and KWS SAAT AG (KWS) requesting a determination of nonregulated status

under 7 CFR part 340 of sugar beet (Beta vulgaris ssp. vulgaris) designated as event H7-1, which has been genetically engineered for tolerance to the herbicide glyphosate. The petition stated that this article should not be regulated by APHIS because it does not present a plant pest risk. APHIS also announced in that notice the availability of a draft environmental assessment (EA) for the proposed determination of nonregulated status.

Following review of public comments and completion of the EA, we published another notice in the Federal Register on March 17, 2005 (70 FR 13007-13008, Docket No. 04-075-2), advising the public of our determination, effective March 4, 2005, that the Monsanto/KWS sugar beet event H7-1 was no longer considered a regulated article under APHIS regulations in 7 CFR part 340.

On September 21, 2009, the U.S. District Court for the Northern District of California issued a ruling in a lawsuit challenging APHIS' determination of nonregulated status of sugar beet event H7-1, finding that APHIS should have completed an environmental impact statement (EIS) prior to making a determination of nonregulated status of sugar beet event H7-1. On May 28, 2010 (75 FR 29969-29972, Docket No. APHIS-2010-0047), we subsequently published a notice of intent to prepare an EIS and proposed scope of study.

National Environmental Policy Act and Record of Decision

To provide the public with documentation of APHIS' review and analysis of the potential environmental impacts of sugar beet event H7-1 and interrelated socioeconomic impacts associated with a determination of nonregulated status of sugar beet event H7-1, an EIS has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508); (3) USDA

regulations implementing NEPA (7 CFR part 1b); and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

A notice of availability regarding the draft EIS was published by the Environmental Protection Agency (EPA) in the Federal Register on October 14, 2011 (76 FR 63922, Docket No. ER-FRL-8999-5) and a notice of availability regarding the final EIS was published by EPA in the Federal Register on June 8, 2012 (77 FR 34041-34042, Docket No. ER-FRL-9003-4). The NEPA implementing regulations in 40 CFR 1506.10 require a minimum 30-day waiting period between the time the notice of availability of a final EIS is published and the time an agency makes a decision on an action covered by the EIS. APHIS has reviewed the final EIS and evaluated the comments received during the 30-day waiting period and has concluded that it has fully and appropriately analyzed the issues covered by the final EIS and those comments. Based on our final EIS, the response to public comments, and other pertinent scientific data, APHIS has prepared a record of decision for the final EIS.

Determination of Nonregulated Status

Based on APHIS' analysis of field and laboratory data submitted by Monsanto/KWS, references provided in the petition, peer-reviewed publications, information analyzed in the EIS, the plant pest risk assessment, comments provided by the public, and APHIS' evaluation of and response to those comments, APHIS has determined that sugar beet event H7-1 is unlikely to pose a plant pest risk and, in fact, is not a plant pest. Accordingly, the petition requesting a determination of nonregulated status is approved and sugar beet event H7-1 is no longer subject to our regulations governing the introduction of certain genetically engineered organisms and to the plant pest provisions of the Plant Protection Act.

Copies of the determination of nonregulated status document and the record of decision, as well as copies of the final plant pest risk assessment and final EIS upon which the determination and record of decision were based, are available as indicated in the ADDRESSES and FOR FURTHER INFORMATION CONTACT sections of this notice.

Done in Washington, DC, this 18th day of July 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.